

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	CRIMINAL NO.: SA-14-CR-926-FB
)	
VASCULAR SOLUTIONS, INC., (1) and)	
HOWARD ROOT, (2))	
)	
Defendants.)	

**THE UNITED STATES' MOTION *IN LIMINE* TO PRECLUDE
FURTHER EVIDENCE AND ARGUMENTS
ENCOURAGING JURY NULLIFICATION**

The United States moves the Court *in limine* for an order excluding further evidence and arguments encouraging jury nullification. Defendants have raised nullification arguments relating to: (1) the utility of instructions for use, (2) internal, non-public FDA deliberations, and (3) FDA's handling of the perforator device of VNUS, VSI's competitor. Defendants' arguments invite the jury to disregard the law and do not relate to any element of the charges in the indictment. The Court should prohibit Defendants from further eliciting or introducing evidence related to these topics because it serves no purpose other than jury nullification.

Defendants theme, from its opening, has been the supposed incompetence of the FDA and its inconsistent application of the law. Such evidence or argument is irrelevant to the charged offenses and precluded under Fed. R. Evid. 402; encourages the inference that because FDA may have been mistaken in the past, it

was in this instance, an inference precluded under Fed. R. Evid. 404; and invites the jury nullification in that it suggests the jury should acquit because of their personal view that the laws at issue are unnecessary.

A juror's duty is to follow the law. Fifth Circuit Pattern Jury Instructions No. 1.04 - "Duty to Follow Instructions." Defendants' practice of mocking or undermining laws regulating the medical device industry improperly encourages jurors to not follow the law and acquit despite the evidence, that is, encourage jury nullification. The Fifth Circuit has rejected such a defense and affirmed a district court's exclusion of evidence or arguments that encourage jury nullification, either directly or by suggestion. *See United States v. Thompson*, No. 99-41007, 2001 WL 498430, at *16 (5th Cir. Apr. 9, 2001) (unpublished) (prohibiting defense from comparing at closing defendant's actions with those that were not prosecuted or immunized). Accordingly, the Court "may block defense attorneys' attempts to serenade a jury with the siren song of nullification. . . ." *Id.* (quoting *United States v. Sepulveda*, 15 F.3d 1161, 1190 (1st Cir. 1993)).

Defendants have raised and are preparing to continue to make at least three jury nullification arguments. First, Defendants have elicited testimony from various sales representatives and doctors regarding the utility of the instructions for use, suggesting FDA requirements regarding these IFUs are ultimately meaningless. *See* Trial Tr. 2109:23-2110:16 (asking whether as a practice a doctor witness read the instructions for use); 2175:3-4 ("some doctors don't ever even read these IFUs, do they?"); 2677:22-2678:4 ("Many of the don't even bother [to read

instructions], do they? That's how important these instructions are for some doctors?").

Second, Defendants have repeatedly tried to raise internal FDA communications for the purpose of undermining the agency's final decisions.¹ Defendants are again poised to raise arguments regarding internal FDA deliberations. Defendants' exhibit list includes numerous internal FDA communications that were not public and not shared with VSI. *See* Exhibit 1 (Nos. 1001-05, 1014-15). The only purpose of such documents would be to question the FDA's handling of VSI's application, which relates to no element of the charges.

Finally, Defendants are using selective prosecution theory to argue for jury nullification. Defendants have already elicited testimony about² and intend to further question FDA's handling of the clearance of VNUS' perforator device. On their witness list, Defendants have identified Sam Nanavati, a former director of regulatory affairs for VNUS. Defendants' exhibit list also contains numerous VNUS 510k submissions, VNUS 10-Qs, and MAUDE reports. *See* Exhibit 1 (Nos. 1200-1212).

The FDA's decision making behind the clearance of VNUS' perforator device has no relevance to whether Defendants' misbranded the Short Kit and engaged in a conspiracy. Defendants' arguments are solely attempts to undermine the FDA and invite jury nullification. *See* Trial Tr. 313:5-8 ("mistake after mistake"); 1323:3-

¹ *See* Trial Tr. 2734:10-2736:23.

² *See* Trial Tr. 1340:1-18 (producing evidence of a mistake by presenting Ogden with only part of an FDA file); 1344:16-25 (asking Ogden if he agrees that FDA ought to review devices on a level playing field).

7 (asking repeatedly if FDA gets it wrong); 1342:25 (pushing Ogden to agree that asking VSI for clinical data was a mistake); 1470:19-71:5 (Court sustaining objection after defense counsel attempts to get Ogden to agree that the FDA doesn't always get it right).

The United States' evidence concerning VNUS relates solely to VSI's motivation to launch the Short Kit. Specifically, the entry of VNUS' FDA-cleared perforator device onto the market forced VSI to respond with the Short Kit. *See, e.g.,* Trial Tr. 370:24-371:22; 583:10-584:4. Beyond the existence of the VNUS' perforator styler on the market, the company is irrelevant to the case. Defendants, in contrast, have sought to question FDA's decision making with regard to the VNUS device³ and are further seeking the testimony of a VNUS regulatory director. Whether FDA made "mistakes" in its approval of the VNUS product provides the jury no information about whether "Vari-Lase products were misbranded because VSI did not provide the FDA with a premarket notification," whether VSI's "labeling did not have adequate directions for use," and whether Defendants conspired to commit these offenses and conspired to defraud the FDA. *See* United States' Proposed Jury Instructions, Doc. No. 172.

Defendants should not be allowed to mount a frontal assault on the medical device laws. Such a defense amounts to jury nullification in that it "turn[s] the trial away from a determination of whether the elements of the offense charged had been proved beyond a reasonable doubt into a wide-ranging inquiry into matters far

³ *See* Trial Tr. 1340:1-18 (producing evidence of a mistake by presenting Ogden with only part of an FDA file); 1344:16-25 (asking Ogden if he agrees that FDA ought to review devices on a level playing field).

beyond the scope of legitimate issues in a criminal trial.” *United States v. Rosado*, 728 F.2d 89, 93 (2nd Cir. 1984). In *Rosado*, defendants mounted a “political defense” by questioning the United States’ involvement in Puerto Rico as opposed to presenting a defense to the charges. *Id.* at 92. Here, too, Defendants’ defense appears to question the United States’ involvement in the regulation of medical devices.

The law does not permit jury nullification evidence, and accordingly, the proffered evidence would be neither relevant nor admissible. Fed. R. Evid. 401, 402. For this same reason, the potential for unfair prejudice and confusion of the issues substantially outweighs the probative value, if any, of the evidence. It should therefore be excluded under Rule 403. *See United States v. Melton*, Criminal No. 3:08cr107-DPJ-LRA, 2008 WL 4829893, at *2 (S.D. Miss. Nov. 4, 2008) (excluding evidence encouraging jury nullification on such grounds).

CONCLUSION

For the reasons stated above, this Court should grant the United States’ Motion *in Limine* to Preclude Further Evidence and Arguments Encouraging Jury Nullification.

Dated: February 22, 2016

Respectfully submitted,

RICHARD L. DURBIN, JR.
United States Attorney

By: _____/s/_____

Bud Paulissen
Bud.Paulissen@usdoj.gov
Texas Bar No. 15643450
Christina Playton
Christina.Playton@usdoj.gov
Texas Bar No. 24028652
Assistant United States Attorneys
601 N.W. Loop 410, Ste. 600
San Antonio, TX 78216
Phone: (210) 384 7025
Facsimile: (210) 384 7028

Timothy T. Finley
Timothy.T.Finley@usdoj.gov
D.C. Bar No. 471841
Charles J. Biro
Charles.Biro@usdoj.gov
Illinois Bar No. 6277139
Trial Attorneys
United States Department of Justice
Consumer Protection Branch
450 5th Street NW, 6th Floor, Ste 6400
Washington, DC 20001
Phone: (202) 307 0050

CERTIFICATE OF SERVICE

I certify that a copy of this pleading was served on defense counsel with the filing of it via the ECF maintained by the United States Clerk on this 22nd day of February, 2016.

_____/s/_____
Charles J. Biro
Trial Attorney